United Nations Environment Programme

EP

Distr.
GENERAL

UNEP/Bio.Div.3/Inf.4
18 June 1990

ORIGINAL: FRENCH

AD HOC WORKING GROUP OF EXPERTS
ON BIOLOGICAL DIVERSITY

Third session
Geneva, 9-13 July 1990

Relationship Between Intellectual Property Rights and Access to Genetic Resources and Biotechnology

(A study prepared for the United Nations Environment Programme*)

* None of the views expressed in the study should be attributed to individual Governments or organizations.

Na 90-2356 - 2098E

/...

INTRODUCTION

1. Any invention pertaining to living matter and living things is at the same time a genetic resource and a technology. Subsequently, the legal framework applicable to genetic resources has always been bound to that applicable to inventions.

2. Nowadays, there is free access to genetic resources, without payment, all over the world. Plant breeders' rights, which protect the breeders, give an exclusive right to commercialization of a variety, but leave free access to the increased genetic resources contained within the variety. This system could be suppressed perhaps.

3. A lot of developed countries have opted for the patenting of genes and try to patent plant varieties and animal breeds. As a result, the exclusive rights will cover not only the invention, but also the resource included therein. This could involve a change in the legal framework governing genetic resources. Such resources would no longer be the common heritage of mankind, but would be owned by States.

4. The system outlined in paragraph 2 above is more desirable, because the transfer of technology is easier. Here the aim is to organize the circulation of genetic resources. Of the two modalities of intellectual property noted above, one must choose that which enables the circulation of genetic resources, i.e. plant variety rights.

I. HISTORY OF THE APPROPRIATION OF GENETIC RESOURCES

A. The initial pre-legal phase: freedom and problems

5. For a long time there were no legal rules to regulate the circulation of genetic resources, but this does not mean that such circulation was without constraints. Farmers exchanged specimens of interest among themselves, but possessiveness was never excluded. Rare and precious plants were frequently monopolized. At the global level, however, seeds circulated as people did. The establishment of the great empires gave rise to a great genetic intermixing. The idea of a free-circulation zone is perhaps the positive element that must be retained.

6. The central object of technical interest was the species. Attempts were made to discover new species, such as the potato. During this period, there was a great reduction in inter-specific variability, heralding the present-day situation in which 90 per cent of the food resources of the planet are based solely on about 30 species. Intra-specific variability was not exploited. The great famine in Ireland, resulting from the destruction of the potato crop due to blight, revealed the dangers of limiting the genetic base of crops.

7. Thus, there were no intellectual property rights, and access to genetic resources was free. However, industrialization and imperialism led to the concentration of genetic know-how and genetic resources in the developed countries, even though the developing countries retained the bulk of the in-situ biological diversity.

/...

B. The second phase: an invention is protected, but there is free access to the genetic resource

1. Establishment of the system governing new varieties of plants

8. Between 1930 and 1960, various industrialized countries passed laws giving the creators of new plant varieties a temporary monopoly on exploitation. In 1961, the convention establishing the Union for the Protection of New Varieties of Plants (UPOV) was signed by a number of industrialized countries. In practice this meant that, through a mechanism based on patent law, anyone who developed a new plant variety was given a monopoly on its commercial exploitation. This right is limited to varieties of plants, and does not include animals, micro-organisms, genes or species. The central object of technical interest became the variety. The emphasis changed from acclimatizing new species to improving them, by progressing from one variety to another within a single species.

9. The law on new varieties of plants differs considerably from patent law, since the monopoly is restricted in two ways. On the one hand, a farmer who has bought a batch of seeds from a seed company is entitled to retain a portion of his crop to resow his field the following year without paying royalties to the creator of the variety, whereas patent law makes such payment obligatory. This is what is called the "farmer's privilege", whereby the farmer pays only once for the technology contained in the batch of seeds he has bought, and he can dispose of all subsequent generations freely and without payment.

10. On the other hand, every creator of varieties is free to use a competitor's varieties, even though they are subject to a monopoly on exploitation. This is what is known as free access to protected varieties as a source of genetic variability. Of course, the seed cannot be produced and sold in competition with the original variety; but a protected variety can be used in the competitor's own breeding process to develop a new variety deriving from the first and containing some of its qualities. If, by cross-breeding, inducing mutations, etc., the competitor succeeds in creating a new variety, he is entitled to apply for a monopoly on its exploitation. The right he then obtains is completely independent of that accorded to the producer of the first variety, and no authorization nor royalty is needed. In other words, competitors are not entitled to dispose freely of the seed as a finished manufactured product; but, freely and without payment, they can dispose of the genetic resource and technology contained in the seed.

11. The subtlety of this system has not always been properly understood and, within the same grain of wheat, not everyone has been able to distinguish between the manufactured product, which is covered by a monopoly, and the genetic resource to which there is still free access without payment. It has often been thought that genetic resources are being subject to captation, which is not quite true. Similarly, plant breeders' rights have often been accused of having led to the genetic uniformity of crops, and this is not quite correct either. Animal breeds are probably more uniform, even though no intellectual property rights are involved. In actual fact, uniformity derives from production and marketing systems, and not from intellectual property rights.

/...

12. The farmer's privilege and free access, without payment, to protected varieties for the purpose of creating new varieties represent a radical difference between plant breeders' rights and patent law. The justification for this difference must lie in the very nature of the object of the invention: what is being protected in this case is not inert but alive. What is more, to create living organisms there must be parent organisms. If there is no free access to these, the creation of original new organisms will become difficult and expensive and will be reserved for very large firms with their own exclusive stock of genetic resources.

13. Under this system, it can be assumed that there is an imaginary "plant gene pool", including all wild plants, all older varieties and all cultivated plants, even if they are protected by plant breeders' rights. This whole genetic pool is freely available, without payment, to all parties to UPOV. Neither of the two main mechanisms for appropriation, State sovereignty and industrial property rights, prevent this. However, this does not mean, that there is no inequality between North and South. Without modern selection technology, the countries of the South are not able to take advantage of the free access to protected varieties to the same extent as the countries of the North. However, the farmers of the South have know-how in plant matters which would certainly enable them to take advantage of the circulation of protected seeds, whether by exercising the farmer's privilege or by crossing such seeds with local varieties. It must thus be regretted that more developing countries have not acceded to the UPOV Convention. At the same time, the existence of this plant varieties law would not prevent compensation mechanisms from being devised where genetic resources are sought in developing countries. Licensing mechanisms, with or without payment, are quite imaginable. It is virtually certain that the system has been criticized or even condemned through a lack of understanding, while its possibilities have by no means been exhausted.

2. The 1983 FAO International Undertaking on Plant Genetic Resources: such resources as part of the common heritage of mankind

14. At about the same time as the new plant breeders rights were developed, the decolonization movement began to bear fruit. Having regained their legal identity in the community of States, the developing countries still remained very dependent in economic matters. They had to undertake the lengthy task of recovering their resources and natural wealth, beginning with what at first sight appeared to be the most important thing, namely mineral wealth (cf. the legal concept of "permanent sovereignty over natural resources").

15. After a certain length of time, the idea emerged that the major plant collections amassed by the industrialized countries in the developing countries followed the same colonial logic as oil production concessions. From a strictly objective point of view the situations were somewhat different; taking away some plants or seeds does not exhaust the genetic resources of the place in which they have been gathered. Economically, however, the phenomenon is identical, although generally it has a smaller scope. The South furnishes the raw materials, without being able to organize the transfer of the technology.

16. Plants originating from the South are utilized in the North in breeding programmes to give an improvement in the dry matter content of tomatoes, increased resistance to certain diseases, etc. and such plants are gathered freely and without payment, whereas the seeds developed from them return after processing and then have to be paid for. Noting this, the developing countries sought recognition for their sovereignty over this natural wealth (the logical consequence of which was the power to authorize or forbid prospecting at their discretion) and the possibility of securing revenue from it. This met with total incomprehension on the part of the industrialized countries: were they to accept that the gathering of isolated specimens, which in no way detracted from the value of the zone or from the equilibrium or variability of the species, could be compared to the exploitation of mineral deposits? Plant life reconstitutes itself. Therefore, it seemed unthinkable to bestow a commercial value on it.

17. In 1983, the two sides met under the auspices of FAO, in mutual incomprehension. The industrialized countries were not yet ready to acknowledge that genetic resources possessed real value. Conversely, the developing countries did not understand that plant breeders' rights made genetic resources freely available to any country joining UPOV, even if the exploitation of varieties constituted a monopoly.

18. Agreement was reached on the fact that plant genetic resources were the common heritage of mankind, though today one might wonder whether that had any meaning, as the participants were not in agreement on the definition of genetic resources. From the economic standpoint, giving this status to plant genetic resources constituted a necessary but signally inadequate step. It should have been accompanied by specific compensation machinery to ensure that the countries which possessed resources were encouraged to undertake conservation activities. As a public good, the common heritage of mankind does not generate revenue. Market mechanisms therefore offer no encouragement for conservation.

19. The main advantage of the International Undertaking on Plant Genetic Resources was that it aroused interest in these questions, an opening for discussion, in which misapprehensions could gradually be dispelled.

C. The third phase: biotechnologies; the patenting, appropriation and widespread marketing of genetic resources

20. With the emergence of biotechnologies, it became difficult to identify objects technical of interest. Genetic resources became subject to greater detail, since the barriers of the species no longer constituted overwhelming obstacles. Any DNA fragment collected anywhere could constitute a genetic resource which would improve any type of living organism. Genetic resources of different types would therefore co-exist: genes; the cellular systems by which they are expressed; conventional genetic structures, such as wild or cultivated plants; or groups, such as varieties; or environments which become "gene pools".

21. Intellectual property law was also undergoing an upheaval. Invention, too, shifted to a more detailed level. In the plant world, invention no longer focused on the variety but on numerous constituent elements - gene fragments, processes, plant tissue, plasmids, cytoplasms, enzymes, proteins, etc. Subsequently, a demand was formulated that intellectual property rights should also cover animals. Finally, the companies that were most active in the field of microbiology sought patent protection for all these inventions,

/...

as they considered rights under the plant varieties law to be insufficiently remunerative. If these rights are replaced by patents and the range of intellectual property is extended to cover "living matter" in its entirety, this will generate a number of changes which it is necessary to understand.

1. From the first patents on living matter to generalized patentability (developments in the United States of America)

22. After some hesitation, a judge in the United States agreed that the time had come to grant industrial property rights in the new sphere of human activity constituted by genetic engineering. Considering micro-organisms, he decided to do away with the principle of the non-patentability of living matter and natural processes. He pointed out that the patent in effect related to a human activity in that the modification of the micro-organism's genome made it a veritable "chemical factory". It was patented as a chemical factory and its capacity as a living organism became unimportant. After the patentability of micro-organisms had been affirmed in 1980 by the United States Supreme Court, it was the turn of maize in 1985, an oyster in 1987 and a mouse in 1988. It should be noted that the courts have not confirmed that animal breeds are patentable, and that the principle is strongly challenged by a number of schools of thought, leading to a call for legislation on the matter.

2. Extension of the decision on patentability to the rest of the world

23. When a country like the United States takes such a far-reaching decision, the question immediately arises of its extension to the rest of the world. The multinational corporations in the chemical, petroleum and pharmaceutical industries, which have a prime interest in the development of the biotechnological mode of production, organized themselves within the International Chamber of Commerce to draw up their demands in legal form. They claimed that rights under the UPOV Convention could not guarantee sufficient remuneration for innovations related to biotechnologies, and asked that the patentability of living matter should be recognized, from the gene fragment to species and genera. The argument was restated by the World Intellectual Property Organization in a number of experts' reports.

24. For two reasons, the offensive was then taken up with the authorities of the European Community. The first reason was that the various countries in the European Community were bound by a European patent convention, which expressly excluded plant and animal varieties from patentability. The obstacle therefore had to be removed. The second reason was that a decision taken at the European level would make it possible to secure at a stroke uniform legal rules valid for the 12 community countries. Consequently, the Industry Department of the EEC Commission (DG III) produced a draft directive on the patentability of living matter which laid the foundations for new patent law applicable to all life. If the directive is adopted, other countries would find it very difficult not to fall into line eventually. In fact, this is the aim of an initiative currently under way within the General Agreement on Tariffs and Trade (GATT).

3. The European proposal for generalized patentability of living matter

25. The extension of patentable inventions affects all realms of living matter - micro-organisms, plants and animals. All manifestations of life are concerned. This means that living things will be patentable, that all the factors in the composition of living things will be patentable (genes, proteins, plasmids, DNA or RNA sequences, tissue, cell lines, probes, etc.), that all organized groups of living things will be patentable (plant and animal species and varieties, if they are products resulting directly from patentable processes), and that all processes will be patentable (processes for the insertion of genes, processes for the expression of genes, for cell culture, for protein production, etc.). Today the combination in greatest demand is an ensemble ranging from the identification of a gene to the organisms in which it is able to express itself - the individual, the line, the breed, the variety, the species, i.e. all realms of living matter. One of the fundamental consequences of the generalized patentability of life, as conceived today, is that the gene becomes the central object of technical interest.

26. Patent law acknowledges neither the farmer's privilege nor free access to patented inventions for the purposes of creation, and this is a fundamental factor in the ongoing transformation. Patent law allows exceptions for purposes of research - a patented process or product may be used in a research programme. However, if the programme succeeds in improving the patented invention, the permission of the patent holder is required in order to exploit the invention, and a royalty must be paid. This is what is known as a dependent invention. The patentee is free to refuse to authorize exploitation. Free access to genetic resources without payment, as stipulated in the plant varieties law, is contrary to patent law.

4. The draft amendment to the UPOV Convention: free or controlled access against payment

27. The proposal concerning patentability clearly raises a crucial problem for breeders of plant varieties. If the UPOV Convention is not amended, the varieties protected by the plant varieties law will be freely available without payment, unlike the genes and varieties protected by patent. In order to avoid this distortion, the members of UPOV have decided to amend the Convention, at least if those who support the concept of the patent continue to block access to genetic resources. In such a case, the rights under the plant varieties law would be brought into line with the patent, although to what extent is not yet known. A dependence mechanism would be instituted, based on the model of patent law.

28. In any event, a shift seems likely from the system of free access to genetic resources without payment to access against payment, though it is not yet known whether access will be free or controlled by the owner of the resource.

5. Common heritage and remuneration: the interpretation of the 1983 Undertaking and the IUCN draft articles on biological diversity

29. It was accepted in 1983 that genetic resources form part of the common heritage of mankind. For many that meant that they were freely available without payment. However, the industrialized countries were unwilling to make a gift of their high-performance varieties, and the developing countries were no longer willing to make their wild plants and local varieties available free of charge. All these reservations were based on errors that are only now beginning to be partly rectified. The first error is that, while the concept of the common heritage of mankind certainly means free access, it does not preclude payment for such access. Indeed, it enables such access to be managed through arrangements which give preference to the developing countries with a view to reducing inequalities. The second error is that protection of an invention under the plant varieties law does not preclude free access to the resource - in fact this is the crux of the plant varieties law.

30. Starting from these erroneous assumptions, States were unlikely to reach agreement. In 1989, however, they reached a compromise which stated that free access does not mean free access without payment. It means that the use of wild plants and local varieties can be subject to payment linked to "farmers rights". It is acknowledged that farmers' rights are rights which farmers in developing countries possess because they have "conserved, improved and made available plant genetic resources". They may therefore receive payment for the utilization of wild plants because they have conserved them, and for the use of local varieties because they have improved them. They make these resources available to the international community as "trustees" for present and future generations of farmers.

31. The free availability of these resources testifies to the fact that they form part of the common heritage of mankind. The fact that they are subject to payment serves to make North South trade more equitable, with farmers' rights being recognized in the same way as plant breeders' rights. Rights under the plant breeders' rights (as provided for under UPOV) have therefore been recognized as compatible with the FAO International Undertaking on Plant Genetic Resources of 1983. The balance struck is typical for the common heritage of mankind concept: free access and compensatory payment.

32. It is necessary to give a precise definition for farmers' rights. The parallel sought between farmers' rights and plant breeders' rights is somewhat dangerous. If equated with intellectual property rights, the farmer's rights would be temporary in nature and restricted to domesticated plants. However, it is clear that this is a means of remunerating work carried out on cultivated plants for thousands of years (it is therefore not temporary), and that the concept must allow for the integration of wild plants. In a way, the purpose is the payment of compensation for the fact that wild plants have not been destroyed in the name of economic development, and this amounts to rewarding an omission. All this should be spelt out.

33. The same kind of delicate balance between freedom of access to the common heritage and the possibility of paying for such access is found in the draft articles on biological diversity of the International Union for Conservation of Nature and Natural Resources (IUCN). Here again, it is recognized that

/...

biological diversity and all the genetic resources contained therein constitute the common heritage of mankind. The possibilities of remunerating use of resource are extensively explored, since any product developed from a genetic resource or by using it, in one generation or another, gives rise to payment of compensation.

6. Rejection of the concept of the common heritage of mankind?

34. If justice has been done to the UPOV Convention with a degree of delay, it may be regretted that FAO has not begun to explore the implications of the patentability of living matter for the legal regime governing genetic resources. If it is decided not to go beyond patent law in its conventional form, there will no longer be free access to genetic resources, even against payment. Such a decision may well have as its consequence an amendment of the UPOV Convention, moving in the direction of a closed system. Logically, the developing countries might then be tempted to follow such a movement. Instead of taking the view that genetic resources form part of the common heritage of mankind, with the international community as the trustee, they might be led to consider that they are the exclusive owners of such resources and that they can deny access to them, at their discretion, to anyone seeking it.

35. One might wonder whether such a trend is not emerging in various forums. There is a need for innovation in the form of users' fees, tax incentives or subsidies to correct market forces. This is an interesting idea. Reliance on market mechanisms makes it possible to avoid the organizational costs associated with administrative management and to ensure long-term operation. However, in the case of plant genetic resources and biological diversity, a number of obstacles would seem to hamper this approach.

36. In the first place, a degree of disaffectedness over the concept of the common heritage of mankind does not seem justified on objective grounds. The concept of the common heritage has lost none of its interest, since it allows free access to be reconciled with possibilities for control and payment. In recent reports, FAO acknowledges that the concept of the common heritage of mankind is not incompatible with the principle of free access against payment. This helps to clarify the debate on plant genetic resources (see "Interpretation of the International Undertaking on Plant Genetic resources" FAO document C89/24). This point cannot be over-emphasized. Both experience and economic theory show that recognition of common ownership in a regime of pure competition tends to lead to the exhaustion of a natural resource. It is therefore vital to insert corrective factors such as charges in order to bring about a degree of efficiency in resource exploitation. Economic thinking holds that unified control of the resource is the ideal solution.

II. INTELLECTUAL PROPERTY RIGHTS AND TRANSFER OF TECHNOLOGY

A. Payment for biological diversity and genetic resources

37. Biological diversity is a collective asset, even if in geographical terms it belongs to one region of the world or another. Management of biological diversity therefore necessitates transnational law, the basis of which must be an international convention. But certain regions of the world have harmed biological diversity more than others. They should provide compensation for the damage caused. Here one cannot speak of all being equal vis-à-vis the burden of preserving biological diversity, but of inequality for purposes of compensation.

1. Biological diversity, national sovereignty and the common heritage of mankind

38. The preservation of biological diversity requires, in the first place, the preservation of zones of diversity, identified as the result of an evaluation operation. Such preservation entails a number of economic sacrifices - no use of fertilizers, for example, no urbanization, re-routing of roads, etc. All these sacrifices present a form of partial expropriation of territory in a higher common interest. In consideration of the sovereignty which is exercised over such territory, the international community must pay compensation.

39. Moreover, because national sovereignty is a fundamental value upon which environmental constraints must not infringe, arrangements for the protection of biological diversity must be adopted by consent and not imposed. Unilateral decisions are to be ruled out, whatever form they may take. Thus, the only possible legal basis is an international convention or regional instruments. But it is necessary to ensure that the convention does not provide for the delegation of power to central agencies whose function would be to draw up standards. Standards should be developed jointly, and applied by the management bodies. The current version of the IUCN draft articles on biological diversity allows for too many cases of delegation of power on fundamental matters to the scientific authorities set up under the draft articles.

40. The inclusion of biological diversity and genetic resources in the common heritage of mankind does not run counter to the principle of national sovereignty or conflict with forms of resource development based on free access against payment. However, this development option is only marginal and does not release the international community from its responsibilities with respect to the conservation of the genetic heritage. The project for the establishment of an international fund to finance the protection of biological diversity is therefore vital. But it seems essential to link the use of the fund with the necessary transfer-of-technology operations. In many cases, monetary compensation for the costs of conservation will not be the most suitable method. Rather than compensation along the lines of debt-for-nature swaps, of which there have been several examples since 1987, we suggest a compensation mechanism based on technology-for-nature swaps. As far as possible, it is necessary to try to treat as a single whole the proposal for an international fund put forward by UNEP and FAO's international fund for plant genetic resources. This would mean that the terms of trade could be dealt with in an overall negotiating process.

41. Annual investments in the conservation of plant genetic resources amount to $50-60 million. This figure represents less than 0.5 per cent of world seed sales, or the equivalent of the R + D budget of the biggest seed firm. Some experts estimate that the cost of the conservation of biological diversity and plant genetic resources amounts to $500 million. This is probably a very low estimate. It might be made more accurate by recourse to technical assessments and recent methods of cost/benefit analysis (models with an "option value" approach).

2. Genetic resources: free exchange and industrial property rights

42. To guarantee the free exchange of genetic resources, the best legal framework is as follows: all the inventions are protected by plant breeders' rights, and all the genetic resources are protected by farmers' rights.

43. GATT is perhaps a good forum for the global negotiations. In order to make the terms of competition more equal among all countries in the world, a way must be found to share out the burden of maintaining the planet's biological diversity, since it will benefit everyone, although the countries of the North have already largely destroyed the diversity that their territories once contained. But these negotiations must be genuinely global and should not cover solely the question of patents, which can only be understood in relation to the maintenance of biological diversity and free access to genetic resources.

44. Regarding an international fund for biological diversity, there would seem to be no alternative to the principle of mandatory contributions. However, it is possible to envisage the payment of royalties when a product or process is derived from the use of protected biological sources. In order to encourage users to declare such a source, special provisions might be included as part of the search procedures for the granting of intellectual property rights. This source of income would be particularly valuable in the case of pharmaceutical products.

45. Payment of royalties might also be applied when the biological source leads to the creation of a process providing a substitute for export goods. In this case, the royalty would be calculated on the basis of the principle of compensation for income forgone by the traditional exporter. Such a solution, which has points in common with the IUCN draft articles, should be the subject of detailed study from both the legal and economic standpoints. If various sources of financing are envisaged (mandatory contributions, voluntary contributions and fees from intellectual property rights), care must be taken to ensure that they are not cumulative in respect of the same item.

B. Technology transfer mechanisms

46. With regard to genetic resources or biological diversity in general, it can be said that access to genetic resources is in a way inseparable from access to technologies. The UPOV Convention gives much attention to the principle of free access to genetic variability. More systematic use of the possibilities it offers seems necessary. Strictly speaking, the transfer of technology cannot be decreed. However, general mechanisms can be provided to strengthen the existing system.

47. Concerning access to genetic resources, the UPOV Convention has various provisions as mentioned above (free access to the protected variety as a source of initial variability, farmer's privileges). These provisions constitute real tools for the transfer of technology. In view of the importance of the principle of free access, much greater use should be made of this Convention. To this end, it would be desirable for the Convention to be applicable to other living organisms and to be signed by the countries of the South, very few of which are members. Such an approach could be advocated in the current GATT negotiations on intellectual property.

48. Access to technologies basically presupposes an increase in the absorption capacity of the countries of the South. From this standpoint, the accent must be on specific technologies which often make use of tacit knowledge and local learning processes. This know-how is built up over time and is not easily transferable, for it cannot be separated from a particular process by which human resources learn. At a time when the potential of biotechnology is often overestimated, it is necessary to focus on research capabilities for the improvement of plants and the technologies associated with them. It is quite impossible to do without these specific technologies. But it is perfectly possible to use biotechnologies, such as in vitro micro-propagation, provided that they are properly learned.

49. As in the case of the protection of areas of biological diversity, investment in the transfer of technology must be focused more on concrete projects than on organizations. The potential of International Agricultural Research Centres (with an annual budget of $260 million) is vital and must be used within a framework of decentralized projects. Other forms of co-operation must be encouraged: co-operation between public research bodies, as well as private/public or private/private co-operation.